

Notice of Allowability

Application No.

10/625,754

Applicant(s)

LEVENTER ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' RCE and papers submitted September 30, 2005.
2. ☒ The allowed claim(s) is/are 29-32.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Drawings Filed April 19, 2004 ARE Acceptable.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 122705.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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EXAMINER'S AMENDMENT AND COMMENTS

Amendment

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel A. Monaco on December 22, 2005.

The amendment to the specification was not discussed during the interview. However, such represents a remedy to clear informality which Applicants themselves attempted to obviate, (see proposed amendment filed April 20, 2005 and October 25, 2005).

The application has been amended as follows:

In the Specification:

At page 1, line 1, the following has been inserted: ---This is application is a continuation of application Serial No. 10/008,516, filed November 8, 2001, now U.S. Patent No. 6,649,607, which [This application] ...---

In the Claims:

In claim 29, penultimate and last line, "50 mg to 1200 mg." has been changed to ---25 mg to 300 mg.---;

Claim 30 has been rewritten as:

30. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of *S*-tofisopam, a prodrug or pharmaceutically acceptable salt thereof,

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substantially free of its *R* enantiomer, and a pharmaceutically acceptable carrier, wherein the amount of *S*-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.---

In claim 31, line 1, "29" has been changed to ---30---.

Examiner's Comments

In claim 29, the dosage range of "from 25 mg to 600 mg" is not explicitly disclosed in the present specification, but would have nevertheless been immediately envisaged by the skilled artisan from the present specification, i.e., is not new matter. In particular, at page 13, lines 25-26 of the present specification, it is stated "A daily dosage range can be between 50 mg and 600 mg per day, usually divided equally into a one to four times a day dosing. Clearly, both 25 mg and 300 are the dosages when each daily dosage is divided into 2 equal doses.

While "2" is not explicitly disclosed as a range of divisions, the disclosure of "divided equally into a one to four times a day dosing", (page 13, line 26), is such a small genus of daily dosage divisions that the skilled artisan would be lead to any one division of 1, 2, 3 or 4.

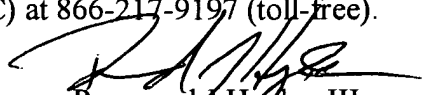
Accordingly, for the reasons above, and those of record, the claims are deemed allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III
Primary Examiner
Art Unit 1614

December 22, 2005